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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
022932		HM12/0619	

IMMUNEX CORPORATION
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GAMBEL P
EXAMINER

1644
ART UNIT | PAPER NUMBER

1644 7

DATE MAILED: 06/19/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 5/16/01

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-14 is/are pending in the application.
Of the above, claim(s) 3-5, 8-13 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1, 2, 6, 7, 14 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Applicant's election without traverse of Group I and the species interferon alpha, GM-CSF and cancer in Paper No. 6, filed 5/26/01, is acknowledged.

Claims 1, 2, 6, 7 and 14 read on the elected invention.

Claims 3-5, 8-13 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected inventions/species.

2. The filing date of the instant claims is deemed to be the filing date of the instant application USSN 09/44027, i.e. 11/19/99, as the priority applications do not appear to provide support for the instant claims as they read on the elected invention (e.g. interferon alpha, GM-CSF and cancer) of the instant application. Therefore, the instant claims may not have the benefit under 35 U.S.C. § 120 of the parent filing dates.

If applicant desires priority prior to 11/19/99; applicant is invited to point out and provide documentary support for the priority of the instant claims. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Applicant should amend the first line of the specification to update the status and relationship of the priority documents.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 6, 7 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over
Lyman et al. (U.S. patent No. 5,843,423; 1449) AND/OR
Brasel et al. (WO 97/12633) AND/OR
Fichelson (Eur. Cytokine Netw 9: 7-22, 1998)
in view of
Kishida et al. (U.S. Patent No. 5,846,928) AND/OR
Cummins et al. (U.S. Patent No. 5,017,371) AND/OR
Srivastava et al. (U.S. Patent No. 6,017,544).

The instant claims are drawn to methods of augmenting immune responses in patients, particularly cancer patients by administering FLT3 ligand (FLT3-L), interferon alpha and GM-CSF.

Lyman et al. teach methods of treating cancer patients by administering FLT3-L in combination with other cytokines, including GM-CSF including treating intestinal damage resulting from irradiation and chemotherapy and stimulating immune responses as well as hemopoietic cells to improve the quality of life of a patient (see entire document; Background of the Invention; Summary of the Invention, including column 3, paragraph 4; column 7; and Claims).

Brasel et al. teach methods of augmenting anti-tumor immune responses by administering FLT3-L in addition to other cytokines, including GM-CSF (see entire document, including Summary of the Invention; page, 4, paragraphs 5-6; page 5, paragraph 3; page 7, paragraph 1; pages 9-1; page 12; Example 3 and Claims).

Fichelson et al. teach the in vivo anti-tumor activities and hemopoietic reconstitution capabilities of FLT3-L, including the use of colony stimulating factors to stimulate progenitor cells in the peripheral blood (see entire document, particularly pages 15-17, In vivo experimental data involving FL and Conclusions and Perspectives).

Lyman et al., Brasel et al. and Fichelson differ from the claimed methods by not disclosing the use of interferon alpha in addition to FLT3-L and GM-CSF to treat cancer patients.

Fichelson et al. also differs from the claimed methods by not disclosing GM-CSF as the colony stimulating factor per se.

Kishida et al. teach methods of treating patients with cancer with interferon alpha (see entire document, including Background of the Invention, Summary of the Invention, Detailed Description and Claims).

Cummins et al. teach methods of reducing side effects of administering cancer therapy utilizing chemotherapeutic agents and radiation therapy with interferon alpha (see entire document, including Background and Summary of the Invention; Detailed Description; Claims) .

Srivastava et al. teach methods of augmenting cancer vaccines with cytokines including interferon alpha and GM-CSF (see entire document; including Summary of the Invention, including column 4, paragraph 6; Detailed Description, including column 12, paragraph 3; Claims.).

Given the teachings of Lyman et al., Brasel et al. and Fichelson et al. to administer FLT3-L in combination with other cytokines including GM-CSF to treat cancer patients by achieving various endpoints in such treatment; it would have been obvious to combine such treatment with interferon alpha, which also provided various endpoints in the treatment of cancer patients, as taught by Kishida, Cummins et al. and Srivastava et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to select a combination of cytokines, including FLT3-L, GM-CSF and interferon alpha to treat human cancer; given the properties of said cytokines to inhibit cancer, to augment immune responses including augmenting immune responses to cancer antigens and to stimulate hemopoietic cells to alleviate the effects of chemotherapy and radiation therapy in cancer patients.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
June 21, 2001